



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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December 1, 2011

Laura A. Brust  
Assistant General Counsel  
American Chemistry Council  
700 Second Street NE  
Washington, DC 20002

Re: FOI Case No. 39419

Dear Ms. Brust:

This is a final response to your November 7, 2011, Freedom of Information Act (FOIA) request addressed to the FOI Officer at the National Institutes of Health. Your request has been forwarded to our office due to our responsibilities under FOIA. You requested a copy of all records related to the publication "Occupational Exposure to Formaldehyde, Hematotoxicity and Leukemia-Specific Chromosome Changes in Cultured Myeloid Progenitor Cells" authored by Zhang et al. (2010) (the "Study") and published in the Journal of Cancer, Epidemiology, Biomarkers & Prevention. The Records requested may be a part of, or otherwise associated with, Grants R01ES017452 (not R01ES01752 per your request) awarded to Luoping Zhang and P42ES004705 awarded to Martyn T. Smith by the National Institute of Environmental Health Sciences of the National Institutes of Health (NIH) (not under the Intramural Research Program of the National Cancer Institute per your request). The Records requested include the following except for the Records in Attachment A to your letter (which the National Cancer Institute already has provided in response to a previous FOIA request):

1. All Records related to the protocol and methodology for conducting the Study. These include all Records concerning:
  - a. Exclusion criteria for Study subjects.
  - b. The frequency-matching methodology that has been applied in the Study.
  - c. Statistical methods applied for evaluation of the data collected, to include assumptions related to the distribution of the aneuploid cells among individuals in the unexposed and exposed Study subjects (i.e., normal or clonal).
  - d. Methods used for conducting the Fluorescence *In situ* Hybridization (FISH) analysis, including the cutoff values for monosomy 7 and trisomy 8, and irrespective of whether or not intact metaphases were required for analysis.
2. All Records related to the information and data obtained regarding the Study subjects. These include all Records (whether in English or Chinese) concerning:

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- a. Original questionnaires administered to Study subjects by trained interviewers requesting such information as occupational history, environmental exposures, medical history and current medications, and past and current tobacco and alcohol use.
  - b. Spreadsheets or other Records that were developed in order to summarize and/or analyze the information collected as part of the questionnaires administered to each Study subject.
  - c. Records identifying the specific factory at which each Study subject was employed.
  - d. Records identifying the specific Chinese or Western medicines used by each Study subject.
  - e. Records containing the laboratory analytical results from the exposure monitoring conducted with UME diffusion samplers worn by each Study subject.
  - f. Data and methods used for estimating 8-hr time weighted average levels for control subjects and exposed subjects.
  - g. Records that provide the Study subjects' individual clinical chemistry results, to include laboratory standardization, laboratory reference values and interlaboratory comparison statistics.
3. All Records related to any analysis, results (including but not limited to photomicrographs), findings and conclusions resulting from use of the protocol and methodology Records requested in (1) above, with respect to the information and data in the Records requested in (2) above, that have been conducted and that are not included in the published summary of the Study. These include all Records concerning:
- a. All FISH analyses of aneuploidy measured *in vitro* in progenitor cells of exposed and non-exposed workers, to include incidence of trisomy of chromosome 7 or monosomy of chromosome 8.
  - b. All FISH analyses of aneuploidy measured by formaldehyde *in vitro* in progenitor cells.

It is Department of Health and Human Services (DHHS) policy to expunge EIN numbers, ERA Commons User Names, personal email addresses, references to unpublished articles, and percentages of effort, wherever they appear throughout the grant material. This information has been removed from the enclosed material.

Enclosed are 108 pages responsive to your request under items 1a, 1b, 1c, 1d, 3a, and 3b. This consists of:

Application for Federal Assistance, Grant #1R01ES017452-01, "Biomarkers of Formaldehyde Exposure and Toxicity," Principal Investigator (PI): Dr. Luoping Zhang, 108 pages

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Requesters who ask for grant applications usually want to receive only material that will help in understanding the process that led to the awards or to improve their own methods of drafting grant applications. Requesters usually do not want material that applicants believe would harm them if released. We have found that the spirit of the FOIA can be enhanced through a spirit of cooperation among requesters of materials and those who submitted the materials.

In this instance, we asked the grantee for advice concerning patent rights and other confidential commercial or financial information and the material that we are furnishing reflects that advice. If you feel that materials have been omitted that should have been made available to you, please write to me and I will consult with the NIH Freedom of Information Officer.

To the extent that your request under item 2f seeks data produced under a National Institutes of Health grant pursuant to the provisions of Office of Management and Budget (OMB) Revised Circular A110, please understand that the provisions of Revised Circular A110 apply to data:

- First produced under a new or competing continuing grant awarded after April 17, 2000, (the day the Department of Health and Human Services amended 45 C.F.R. Part 74 to implement Revised Circular A110); and
- Cited publicly and officially by the Federal Government in support of an agency action that has the force and effect of law.

Because the data you have requested does not meet one or both of the above referenced criteria, NIH will not forward your request under item 2f to the grantee for response. For more information regarding the application of Revised Circular A110, please visit the Office of Extramural Research website at [http://grants.nih.gov/grants/policy/a110/a110\\_guidance\\_dec1999.htm](http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm).

You have the right to appeal this determination that Revised Circular A110 does not apply to the data you have requested. Should you wish to do so, you must send your appeal within 30 days of receipt of this letter to the Director, News Division, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, 7700 Wisconsin Avenue, Suite 920, Bethesda, Maryland 20857, following the procedures outlined in Subpart C of the enclosed regulations, 45 C.F.R. Part 5. Please mark the envelope and appeal letter "FOIA Appeal."

The Division of Extramural Research and Training (DERT) searched its files and no records responsive to your request under items 2a through 2g were located. This is due to the fact that these types of records are not required by DERT as part of the administration of grants and are not in our possession. In addition, the grant records for P42ES004705, "Biomarkers of Benzene Exposure and Leukemia Risk," PI: Dr. Martyn T. Smith, were reviewed and found to be non-responsive to your request because the grant looks exclusively at benzene exposures, not formaldehyde exposure. While we believe that an adequate search of appropriate files was conducted for the records you requested, you have the right to appeal this determination that no records exist under items 2a through 2g which would be responsive to your request. Should you wish to do so, please refer to the appeal information provided in the above paragraph.

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In certain circumstances, provisions of the FOIA and DHHS FOIA Regulations allow us to recover part of the cost of responding to your request. Enclosed is an invoice for \$240.80 to cover these costs.

Sincerely,

A handwritten signature in cursive script that reads "Kim Minneman".

Kim L. Minneman  
Freedom of Information Coordinator

Enclosures:  
FOIA Regulations  
Invoice (2 pages)  
108 pages